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Government of India
Ministry of Commerce & Industry
Department of Commerce
Directorate General of Foreign Trade
Udyog Bhawan

Notification No. 19 /2015-2020
New Delhi, Dated: 4 August, 2016

Subject: Import/export policy for Human Biological Samples for commercial purposes: amendment Schedule – 1 (Import Policy) and Schedule – 2 (Export Policy) of ITC (HS), 2012.

S.O. (E): In exercise of powers conferred by Section 3 of FT (D&R) Act, 1992, read with paragraph 1.02 and 2.01 of the Foreign Trade Policy, 2015-2020, as amended from time to time, the Central Government hereby inserts Import Policy for Human Biological Samples for commercial purposes under General Notes 17 to Schedule – 1 (Import Policy) and Export Policy for Human Biological Samples for commercial purposes under General Notes 4 to Schedule – 2 (Export Policy) of ITC (HS), 2012 as under:

“The import of human biological samples by the Indian diagnostic laboratories / Indian Clinical Research Centres for lab analysis / R & D testing or export of these materials to foreign laboratories should be permitted by Customs authorities at the port of entry / exit without prior approvals (import licence / export permit) from any other Government agency, provided the concerned Indian company / agency submits an undertaking that they are following and will follow all the applicable rules, regulations & procedures for safe transfer and disposal of the biological samples being imported / exported as per the related norms / regulations set by WHO* / DGFT** [SCOMET items in Export Policy of ITC (HS), 2012, Schedule – 2 (Export Policy)] / Ministry of Environment, Forests and Climate Change***, Government of India, to the Customs authorities at the port of entry / exit along with the details of such samples”.

2. Effect of this Notification: Policy condition for import /export of human biological samples for commercial purposes is laid down.

* (i) http://apps.who.int/iris/bitstream/10665/149288/1/WHO_HSE_GCR_2015.2_eng.pdf?ua=1
(ii) <http://www.who.int/csr/resources/publications/biosafety/en/Biosafety7.pdf>

** <http://dgft.gov.in/exim/2000/scomet/scomet2011.pdf>

*** (i) <http://envfor.nic.in/legis/env/env1.html>
(ii) <http://envfor.nic.in/legis/hsm/hsm3.html>

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